IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPELLANT: | Max R. Motyka |
| SERIAL NO.: | 10/829,468 |
| FILING DATE: | 04/21/2004 |
| CONF. NO.: | 6421 |
| FOR: | NON-GMO METAL AMINO ACID CHELATES AND NON-GMO METAL AMINO ACID CHELATE-CONTAINING COMPOSITIONS |
| ART UNIT: | 1616 |
| EXAMINER: | Ernst V. Arnold |
| DOCKET NO.: | 00015-22305 |

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DATE OF DEPOSIT: October 8, 2008

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Brenda Wiseman
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APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. § 41.41

Commissioner for Patents
P.O. Box 1450
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Sir:

Appellants submit this Reply Brief in response to the Examiner's Answer, mailed on August 19, 2008, in connection with their Appeal Brief, filed on June 9, 2008, which was filed in response to the final rejection of the Patent Office, mailed January 24, 2008, in the above-identified application.

## STATUS OF CLAIMS

Claims 34-53 remain pending and have been rejected. Claims 1-33 have been canceled. The claims on appeal in this application are claims 34-53.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented for review are:

a. whether claims 34-36, 41-45, and 50-53 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu");

b. whether claims 34-36, 41-45, and 52-53 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424");

c. whether claims 43-45, 50-51 and 53 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427"); and

d. whether claims 34, 37-40, 43 and 46-49 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Hsu in view of an academic article entitled "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi").

## ARGUMENT

### A. Examiner's Answer

The following numbered paragraphs summarize the Examiner's rejections and the Examiner's response to the Appellants' arguments. The following section B addresses those arguments that have been presented by the Examiner in response to the Appellants' previous arguments. The Appellants refer the Board of Appeals to the Appeal Brief for a more complete summary of Appellants' positions, as supplemented by the present Reply Brief.

1. In rejecting claims 34-36, 41-45, and 50-53 under 35 U.S.C. § 102, the Examiner alleges that Hsu teaches metal amino acid chelates. Even though Hsu does not teach non-GMO products or materials, the Examiner "interprets the selection of specific reagents by Hsu to produce the metal amino acid chelate as reading upon instant claims 35 and 36." Examiner's Answer, page 4.

2. In rejecting claims 34-36, 41-45, and 52-53 under 35 U.S.C. § 102, the Examiner alleges that Ashmead '424 teaches metal amino acid chelates. The Examiner does not specifically address the non-GMO element in this rejection, but states "[o]btaining metal ions and amino acids to make the composition reads upon instant claims 44 and 45." Examiner's Answer, page 5.

3. In rejecting claims 43-45, 50-51, and 53 under 35 U.S.C. § 102, the Examiner alleges that Ashmead '427 teaches metal amino acid chelates. . The Examiner does not specifically address the non-GMO element in this rejection, but states that "Ashmead et al. claim the method of preparing the composition." Examiner's Answer, page 6.

4. In rejecting claims 34, 37-40, 43, and 46-49, the Examiner alleges that Hsu in view of Izumi teaches a method of producing metal amino acid chelates other than protein hydrolysis.

5. In response to Appellants' argument that the references cited by the Examiner do not discuss or disclose the present method of producing non-GMO amino acid chelates, the Examiner asserts that "the metals and amino acids are inherently/intrinsically not from a genetically modified organisms [sic]." The Examiner alleges that the "Appellant appears to be applying a label of non-genetically modified organism to the sources as a means to instill novelty to a well known process" and further seems to emphatically state "**There is nothing new here.**" Examiner's Answer, page 8. Additionally, the Examiner questioned one of the arguments made by Appellants regarding making a non-GMO determination. See Id. at 9.

B. 102 Rejections of Independent Claims 38 and 46

Throughout the present prosecution, Appellants have attempted to explain the correct standard needed to establish anticipation. The Appellants have submitted 102 case law to the Examiner and have argued that the Examiner must show each and every element in rejecting the present method claims. Additionally, Appellants have explained that the product-by-process inquiry cited by the Examiner throughout the prosecution does not apply to method claims, i.e., patentability of a method is independent of patentability of a product. Appellants have explained that a single product may be produced by a number of patentable methods. However, Appellants are unsure if the Examiner has considered

this critical difference as the Examiner has maintained the present 102 rejections by referencing the product in the present Examiner's Answer.

Notably, the Examiner has never argued that any of the presently cited references explicitly teach a non-GMO composition. Instead, at best, the Examiner is relying on inherency. As such, in order to establish a proper 102 rejection, the Examiner must show that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. However, the Examiner has not done so in rejecting the present method claims.

There are several "missing descriptive matters" in the present case for both independent method claims. For claim 34, none of the cited art teaches selecting an amino acid determined to be non-GMO or selecting a metal source determined to be non-GMO. The non-GMO determination is critical in providing a non-GMO metal amino acid chelate composition that is know to be non-GMO. For claim 43, none of the cited art teaches formulating a non-GMO metal amino acid chelate by selecting an amino acid determined to be non-GMO and selecting a metal source determined to be non-GMO; or administering the non-GMO metal amino acid chelate composition to a subject.

To be clear, both independent claims 34 and 43 specifically require an affirmative non-GMO determination steps with respect to both the amino acid source and the metal source. Further, the final product must also be non-GMO, which according to the definition in the specification of non-GMO, is quite limiting. Relevant portions of the definitions from the specification are provided herein for the Board's convenience, as follows:

> The term "GMO" is an acronym for the term "genetically modified organism(s)."
>
> The term "GMO derivative" applies to any substance produced from, but not containing a genetically modified organism.
>
> The term "non-GMO" herein includes compositions that are not GMOs, and also are not derived from GMOs. In other words, non-GMO compositions are not genetically modified of themselves, and are prepared by processes other than those which include the use of genetically modified organisms. Thus, amino acid chelates prepared in accordance with embodiments of the present invention, such as for human, animal, or foliar application, must not include or be produced with the utilization of genetically modified organisms.

None of the references provided by the Examiner refer to any such affirmative step of determination as required by claims 34 and 43, and further, as the final product must also be non-GMO, there is no teaching or suggestion in any of the references that the chelates described therein unambiguously meet this criteria. As such, Appellants contend that the two independent method claims and subsequent dependent claims are clearly distinct over the cited references.

Appellants wish to address the Examiner's arguments as presented in the Examiner's Answer. First, the Examiner has stated that "the metals and amino acids are inherently/intrinsically not from a genetically modified organisms [sic]." Even if this is true, these are method claims. In other words, if an amino acid composition were prepared that is accidentally or incidentally totally non-GMO, it would not read on these claims, because an affirmative determination step is required. In order to label a product as non-GMO, one would have to make these affirmative determinations, which is clearly not done in any of these references. Appellants submit that the Examiner is attempting to replace explicit teachings with mere assertions. Regardless, such an argument has no merit regarding the present method claims as described above because these methods require an affirmative non-GMO determination of the materials used in making the

present non-GMO product. Appellants submit that if the methods of the prior art do not teach this element, the present rejections are fundamentally flawed. Throughout the history of the present prosecution, Appellants have reminded the Examiner that patentability of the present method does not depend on the patentability of the product. In other words, even if non-GMO metal amino acid chelates exist prior to Appellants' product, such a finding would not negate patentability of the present method claims. The appropriate standard is whether the prior art teaches each and every element of the method claims. Appellants submit that the Examiner has not provided any reference, or combination of references, that teach an affirmative non-GMO determination for an amino acid chelate preparation. Such a glaring omission is fatal to the PTO's arguments based on the explicit requirements for a 102 rejection, as discussed herein, the Appeal Brief, and throughout prosecution.

Appellants submit that this fundamental misunderstanding is further underscored in the present Examiner's Answer where the Examiner states that "Appellants make a confusing remark" and that "Applicant is correct that a determination of non-GMO source is superfluous and that would seem to undermine Appellant's position rather than support it." Examiner's Answer, page 9. The Examiner simply does not understand Appellants' present position.

To be clear, Appellants submit that in order to read upon the present claims, the Examiner must show the element of a non-GMO determination in the prior art. Further, Appellants submit that the only way the present method step of performing a non-GMO determination would be superfluous is if it were impossible to make a GMO amino acid chelate. In that event, the Examiner could argue that any disclosed method would

inherently provide a non-GMO metal amino acid chelate (again, if GMOs did not exist). However, Appellants note that the Examiner has never argued that GMOs do not exist. Furthermore, Appellants note that such an argument would be wholly without merit as it is common knowledge that GMOs do exist.

Second, the Examiner has stated that the "Appellant appears to be applying a label of non-genetically modified organism to the sources as a means to instill novelty to a well known process" and further states "**There is nothing new here.**" Such a statement shows a fundamental misunderstanding of the current method and disregards the standards set forth to establish a proper 102 rejection. Regardless of the Examiner's feelings regarding the present claims, Appellants submit that the Examiner has not shown each and every element of the present method claims nor established such elements through inherency.

Appellants also wish to address the Examiner's inherency comment with respect to the present method claims. Specifically, the Examiner has argued that one skilled in the art would obtain a metal and amino acid from a non-GMO source, "which is inherent in the method." See Final Office Action, mailed January 24, 2008, page 9. As the Examiner is particularly relying on this doctrine, Appellants wish to provide the Board with applicable case law. Specifically, the Federal Circuit Court of Appeals stated "[u]nder the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element 'is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill' (citations omitted). Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002). The Court further states that

"'[i]nherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art'" (citations omitted). Id. As such, Appellants submit that the appropriate standard in establishing an anticipatory rejection through inherency has been well defined by the courts.

Appellants submit that the PTO has not established that a non-GMO determination is necessarily present in any of the cited references. Specifically, none of the references indicate that a non-GMO determination was made, needs to be made, or should be made. As such, Appellants submit that the Examiner's reliance on inherency is inappropriate and cannot serve to establish a proper 102 rejection.

As the present claims contain elements not taught in any of the cited references, alone or in combination, Appellants respectfully request that the Board overturn the present rejections.

## CONCLUSION

Appellants respectfully submit that the claims on appeal set forth in the Appendix of Appellants' Appeal Brief are patentably distinct from the asserted prior art references. Particularly, none of the asserted references, or combinations of references, teach each and every element of the claimed invention.

For these reasons, Appellants respectfully request that the Board of Appeals reverse the rejections and remand the case to the Examiner for allowance.

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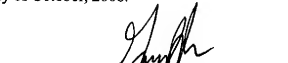
Dated this 8th day of October, 2008.



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